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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,795	08/14/2001	Arnon Shani	U013484-1	3790

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EXAMINER

JIANG, SHAOJIA A

ART UNIT PAPER NUMBER

1617

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856,795

Applicant(s)

SHANI ET AL.

Examiner

Shaojia A. Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53,56,58-71,73-90,92-96,98-103,105,106,109 and 112-114 is/are pending in the application.
- 4a) Of the above claim(s) 64-69,74,83-88,105 and 106 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53,56,58-63,70,71,73,75-82,89,90,92-96,98-103,109 and 112-114 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicant's amendment and response filed on April 18, 2005 wherein claims 72, 77, and 104 are cancelled and claims 53, 56, 58-71, 73-76, 78-90, 92-96, 98-103, 109 and 112-113 have been amended and claim 114 is newly submitted. Claims 1-52, 54-55, 57, 91, 97, 107-108, and 110-111 are cancelled previously.

As recorded in the previous Office Action November 17, 2004, claims 64-69, 74, and 83-88 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

As discussed in the previous Office Action November 17, 2004, claims 105-106 drawn to the invention of a method for the sustained release of a volatile material and a method for treating a volatile material herein that is independent or distinct from the invention originally claimed of the invention originally drawn to the composition herein and the process for preparing the composition herein. The original invention and the claimed invention (claims 105-106) are separate and distinct, related as product and method of use,. See MPEP § 806.05(h). Moreover, According to MPEP § 706.07(h), Applicant cannot switch inventions in RCE.

Therefore, claims 105-106 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

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Currently, claims 53, 56, 58-63, 70-71, 73, 75-82, 89-90, 92-96, 98-103, 109 and 112-114, and 64-69, 74, and 83-88 (nonelected species), and 105-106 (nonelected invention) are pending in this application.

Claims 53, 56, 58-63, 70-71, 73, 75-82, 89-90, 92-96, 98-103, 109 and 112-114 are examined on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 53, 56, 58-63, 70-71, 73, 75-82, 89-90, 92-96, 98-103, 109 and 112-114 as amended now are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment submitted April 18, 2005 with respect to amended claims has been fully considered but is deemed to insert new matter into the claims since the specification as originally filed does not provide support for "An aqueous dispersion comprising a plurality of water soluble beads dispersed in water, each of the water insoluble bead beads comprising...". Contrary to this limitation "water **soluble** beads" in the amended claims, the original specification clearly discloses in the title of the claimed

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invention "SUSTAINED RELEASE POLYMER-BASED WATER INSOLUBLE BEADS"

(emphasis added); the first paragraph of the specification teaches:

"The present invention relates to a sustained release dispersion of water insoluble beads and to a process for the preparation thereof. More particularly, the present invention relates to a sustained release dispersion of water insoluble beads each bead comprising a polymeric matrix comprised of a protein and a polysaccharide and containing at least one volatile hydrophobic component for release therefrom in atmospheric air." (emphasis added).

Thus, the claimed invention is directed to "SUSTAINED RELEASE POLYMER-BASED WATER INSOLUBLE BEADS", not water soluble beads, nor an aqueous dispersion.

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 53, 56, 58-63, 70-71, 73, 75-82, 89-90, 92-96, 98-103, 109 and 112-114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Connick (4,401,456) and Nitto Electric Ind Co. (Abstract, JP58121212) in view of Cohen et al. (US 4,795,642, PTO-892) and Meinke et al. (Journal of Economic Entomology, 1989, Vol 82, 1830-1835).

Connick discloses water insoluble beads in a sustained release polymer matrix comprising droplets of an oil dispersed in water emulsion in a polymeric matrix (see col.2 lines 45-58 and Examples therein), surface active agents broadly, aliginate (the particular polysaccharide), bioactive material (one volatile hydrophobic component herein), and water, that have the same functions as claimed herein, i.e., known to release bioactive material or agents from the water insoluble beads into atmospheric air over a period times, e.g., hours or days; and the process for preparing such a sustained release, polymer, and water insoluble beads therein. Connick also discloses the size of beads therein is 0.1-5 mm, 0.8-2 mm, or 0.1-6 mm; and the gellant is a calcium solution; a bioactive material may be herbicide or insecticide. See abstract, col.1, col.3-4, col.5 lines 1-16, Examples 1-14 and claims 1-11.

Nitto et al. discloses a sustained release, polymer, and water insoluble gel-like body comprising sodium polyacrylate compound having at least one epoxy group per molecule wherein its polymerization degree is 500-5000, cationic surfactant, volatile substance which is in emulsion form, and water; the volatile substance which may be a perfume repellent, attractant, insecticide, and fungicide, is used in amount of 30% or less based on the total weight of the body. See abstract.

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The prior art does not expressly disclose the employment of gelatin in the beads of Connick, a sustained or controlled release system. The prior art does not expressly disclose that the particular volatile component may be pheromone such as gosspluer.

Cohen et al. discloses a controlled-release pharmaceutical composition in a unit dosage form comprising both gelatin and polysaccharide, co-solvents, aqueous solution, surfactants, for releasing pharmaceutical actives in an controlled or sustained manner and the process for making that (see abstract, col.2 lines 14-31, in particular Example I-II at col.6-7).

Meinke et al. discloses that the particular bioactive material, pheromone, is known to be used in a sustained release, polymer, and water insoluble delivery system for western corn rootworm. See abstract and the entire article.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ gelatin in the beads of Connick, a sustained or controlled release system, and employ the particular volatile component such as pheromone (gosspluer) in the instant claimed beads.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular surfactant such as a protein, gelatin, in the instant claimed beads, since first, surfactants are known to be used in the beads of Connick. Secondly, gelatin is a well known surfactant and well known in the art to be useful in a sustained release, polymer, and water insoluble delivery system, for example, the controlled-release pharmaceutical composition of Cohen et al. comprising

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both gelatin and polysaccharide, co-solvents, aqueous solution, surfactants, for releasing pharmaceutical actives in an controlled or sustained manner.

Therefore, one of ordinary skill in the art would have reasonably expected that gelatin would be useful in the delivery systems of Connick and Nitto as a surfactant.

Additionally, one having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular volatile component such as pheromone (gosspluer) in the instant claimed beads since the employment of bioactive material broadly such as a perfume repellent, attractant, insecticide, and fungicide, is known in the delivery systems of Connick and Nitto. Pheromone as herbicide or insecticide is also known to be useful in a sustained release, polymer, and water insoluble delivery system for western corn rootworm. Therefore, one of ordinary skill in the art would have employed the particular volatile component such as pheromone in the instant claimed sustained release system.

Response to Argument

Applicant's arguments filed April 18, 2005 and Applicant's declaration of Shlomo Magdassi filed February 2, 2004 with respect to this rejection under 35 U.S.C. 103(a) in the previous Office Action have been fully considered but are found persuasive as to the nonobviousness of the claimed invention over the prior art as further discussed below.

Applicant's assertion that "Connick teaches away from making the beads insoluble and also teaches away from a dispersion of the beads" is not found persuasive, since first, the instant claims recite "water insoluble beads" (see the

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independent claim 53). Second, Connick clearly teaches a dispersion of the beads (see Connick, col.2 lines 55-58).

Applicant's declaration of Shlomo Magdassi under 37 CFR 1.132, submitted February 2, 2004, is insufficient to overcome this rejection under 35 U.S.C. 103(a) for the following reasons. Applicant's testing results and data shown in the declaration herein have been fully considered but are not deemed persuasive as to the nonobviousness and/or unexpected results of the claimed invention over the prior art.

Note that Shlomo Magdassi states "To test the effects of gelatine on the release rate of pheromones from calcium-alginate based microcapsules and to support the idea that besides being a simple surfactant in the prepared emulsions gelatine also acts as an inhibitor of the pheromone release the following formulations were prepared" (emphasis added, see page 1 of the declaration). Nevertheless, Shlomo Magdassi's statement is seen to be absent any supporting data since the declaration merely presents the release rate of dodecyl acetate from different concentrations of gelatine in microcapsules (see Exhibit 4). One of ordinary skill in the art would recognize that dodecyl acetate and pheromones are neither structurally similar or related to each other, nor have similar properties. Thus, the testing results of dodecyl acetate are not considered to support Shlomo Magdassi's statement above.

Therefore, the declaration is not seen insufficient to rebut the prima facie case herein.

Thus, the clear explanation of pointing out exactly what facts are established therein and relied upon by applicant is not seen in the declaration and specification (see

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page 20). Applicant has the burden to explain the experimental evidence. See *In re Borkowski and Van Venrooy* 184 USPQ 29 (CCPA 1974).


For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
July 5, 2005